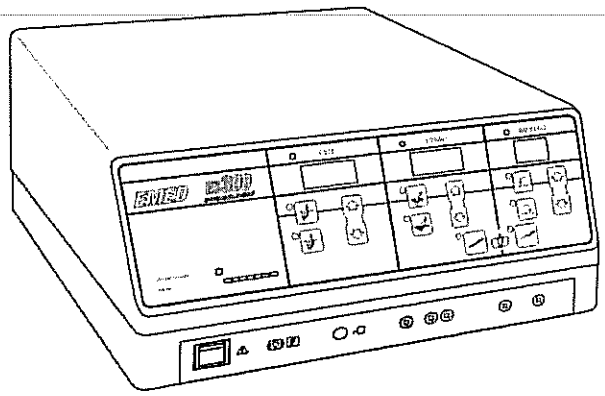
ELECTROSURGICAL SYSTEM
ES300

OPERATION MANUAL



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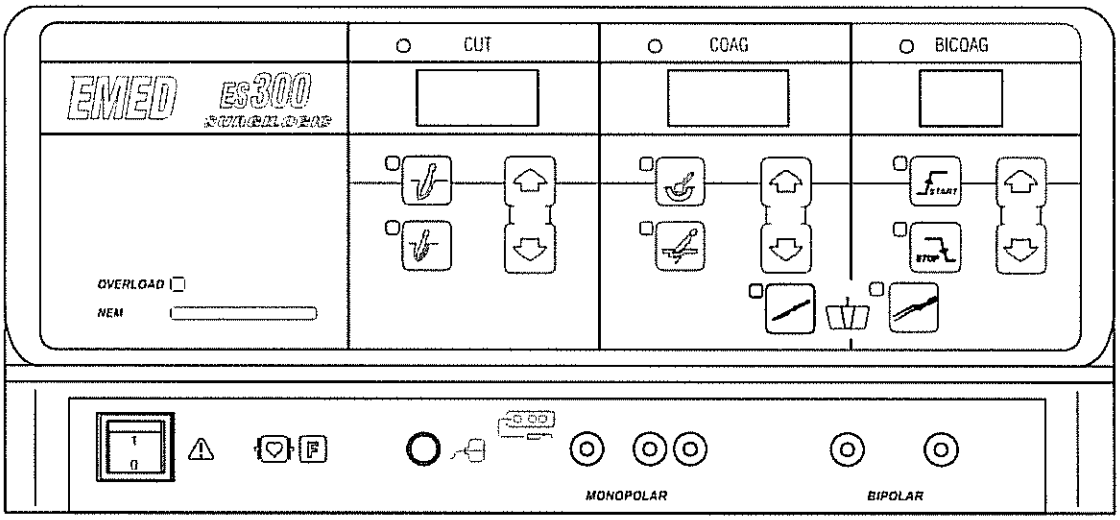


Fig. 1. Frontside view of ES300 system.

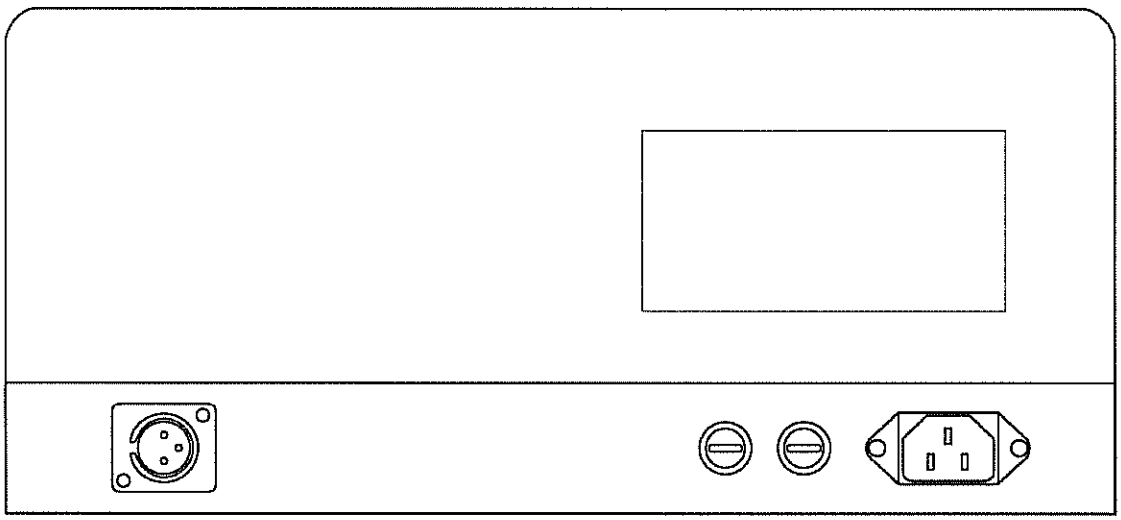


Fig. 2. Backside view of ES300 unit.

1. Purpose of the ES300 system

The electrosurgical system ES300 is an all-purpose diathermy based on high-frequency current flow. ES300 is designed for use in electrosurgical treatment.

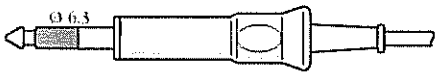
The ES300ystem may be used for cutting and coagulation in open surgery. It is also compatible with laparoscopes and fiberscopes. As the system is equipped with a CF-type (floating) output, it may be used in the central nervous system and the heart.

- pure cutting,
- blend cutting with hemostasis,
- soft coagulation,
- forced coagulation,
- bipolar coagulation.

1.1. Accessories for electrosurgical operations

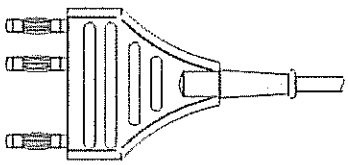
The system is equipped with high-quality surgical accessories permitting a variety of treatment measures to be performed in general surgery, vascular surgery, gynaecology, oncology and other fields.

The connection sockets for the neutral electrode output is made in accordance with the 6.35 mm 1-pin standard (Fig. 3, item 2)



Neutral electrode plug

The socket of the monopolar active electrode (Fig. 3, item 3) is also made in accordance with the so-called 3-pin standard

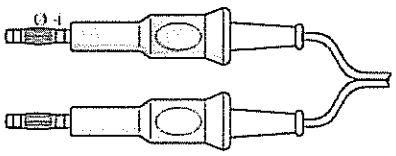


Active electrode plug

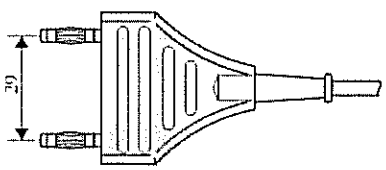
Monopolar endoscope plug

Standard monopolar electrodes with the following diameters may be connected to the system:
- 4 mm - using handles with 4 mm diameter,
- 2.4 mm - using handles with 2.4 mm diameter.

The socket of the bipolar output (Fig. 3, item 4) is made in accordance with the 2-pin 4mm standard.



Two-part bipolar plug



2-pin bipolar plug

2. Technical data for the ES300 system

Table 1 shows the technical data for the electrosurgical system ES300.

SUPPLY	
Supply voltage	230 V ±10% 50 Hz
Rated power input	500 W
SAFETY CONDITIONS	
Class	I
Type	CF
Low-frequency leakage currents	Acc. to IEC 601-1
High-frequency leakage currents	Acc. to IEC 601-2-2
Generator working frequency	version dependent, from 300 to 450 kHz kHz
Defibrillation impulse resistance	acc. to EN60601-1
CONTROL SYSTEM FOR NEUTRAL ELECTRODE APPLICATION	
Optical indication	8 levels
Required resistance (at least 1 green-coloured segment lighted)	< 240 Ω
POWER OUTPUT IN MONOPOLAR CIRCUIT	
Pure cut	250 W for 300 Ω
Blend cut	150 W for 300 Ω
Soft coagulation	150 W for 150 Ω
Forced coagulation	150 W for 300 Ω
POWER OUTPUT IN BIPOLAR CIRCUIT	
Coagulation	99 W for 40 Ω
OTHERS	
Generator dimensions	340 x 360 x 160mm
Weight	6 Kg

Table 1. Technical data for the ES300 system.

3. List of components

Table 2 shows standard components of the electrosurgical system ES300.

ITEM	ITEM DESCRIPTION	PCS.
1	ES 300 generator	1
2	Supply cable 4.5m	1
3	User manual	1
4	Guarantee document	1

Table 1. Standard system components.

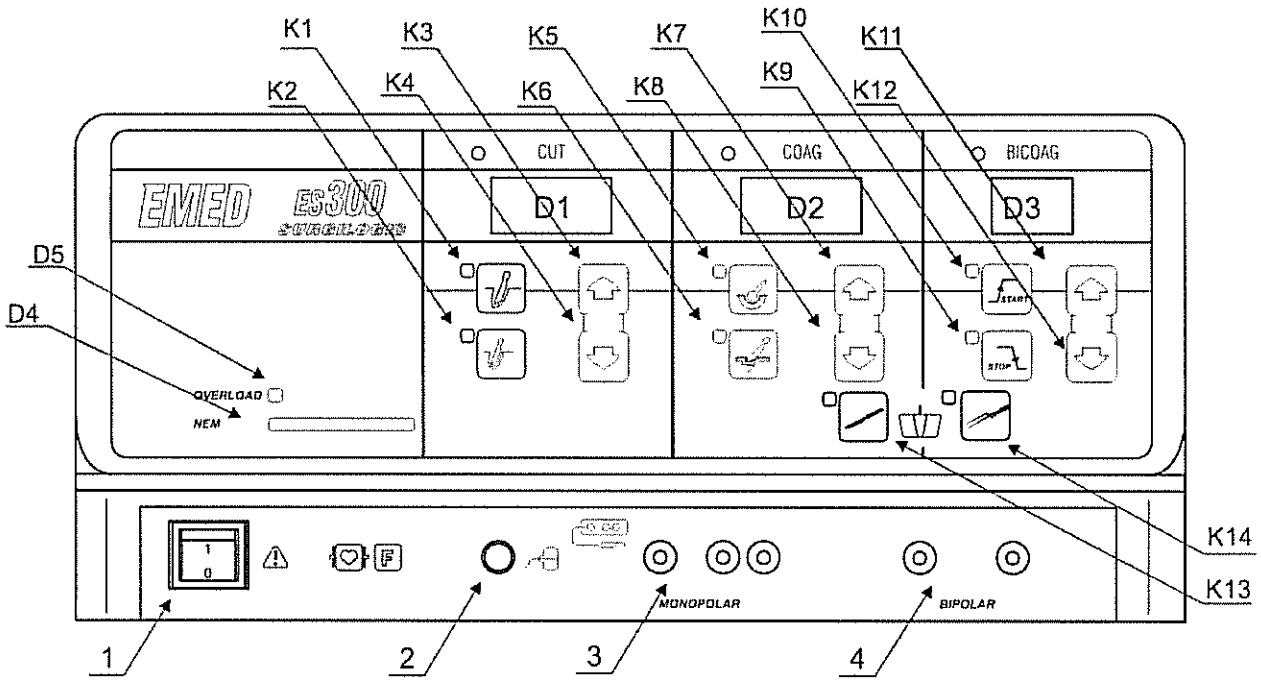


Fig. 3. Frontside view of the ES300 unit.

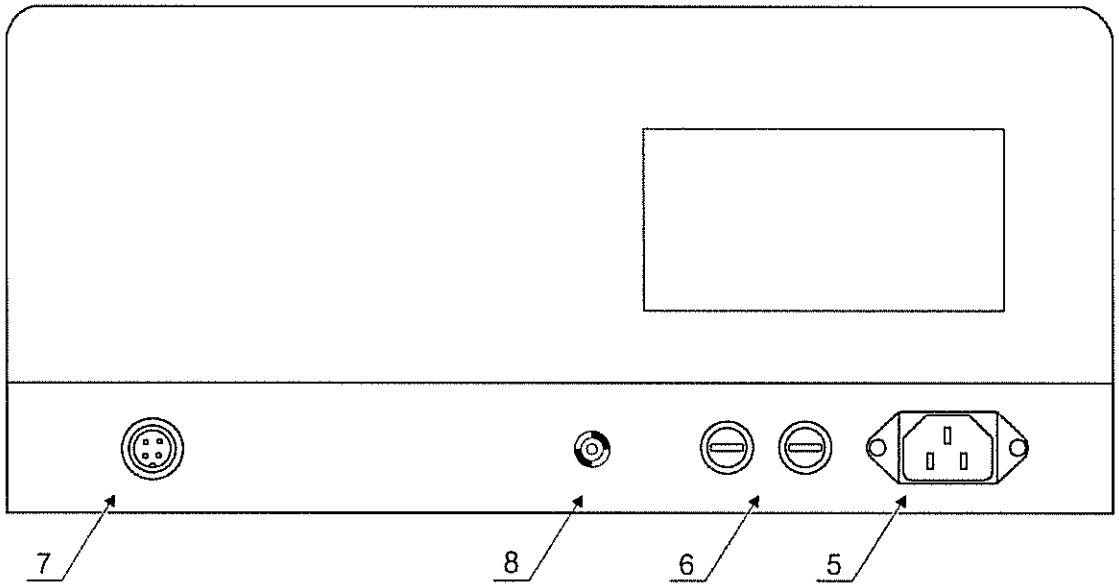


Fig. 4. Backside view of the ES300 unit.

4. Look and construction

The system encasing is made of plastic material without ventilation openings. It is easy to keep the system clean; it can be cleaned with disinfectants.

On the back wall of the encasing there are (Fig. 4):
- the socket of the mains power lead (5),
- the socket of the mains fuses 250V/4 A (6),
- the socket of the double foot-operated switch (7),
- additional grounding pin (8).

On the front wall of the encasing there are (fig. 3):
- the mains switch (1),

- the sockets of:
    - the neutral electrode (2),
    - the monopolar electrode (3),
    - the bipolar electrode (4),

- the selection push-buttons for operation types:
    - pure cut (K1),
    - blend cut (K2),
    - soft coagulation (K5),
    - forced coagulation (K6),
    - bipolar coagulation time limit (K9),
    - bipolar automatic start (K10)

- the power control push-buttons:
    - cut - increase (K3) and decrease (K4),
    - coagulation - increase (K7) and decrease (K8),
    - bipolar coagulation - increase (K11) and decrease (K12),

- push-buttons for working modes of the foot-operated switch:
    - monopolar output control (K13),
    - bipolar output control (K14),

- set power displays for:
    - cut (D1),
    - monopolar coagulation (D2),
    - bipolar coagulation (D3),

- line display - neutral electrode application control (D4),

- system overload control (D5).

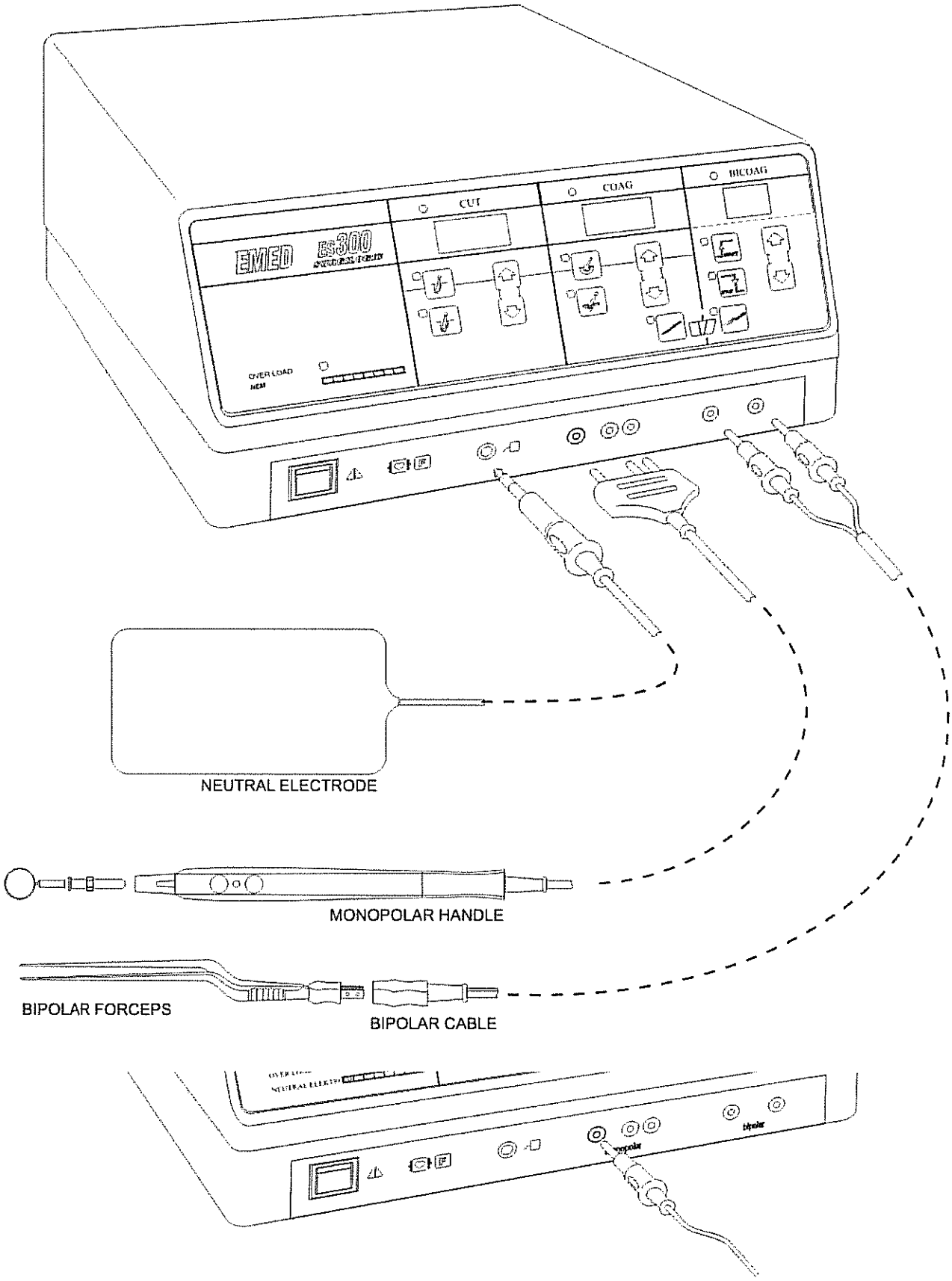


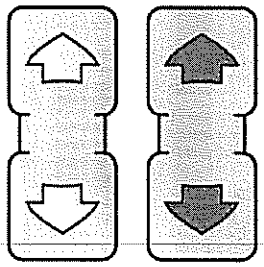
Fig. 5. Mode of connection of accessories to the ES300 system and mode of laparoscope connection.

5. Preparation of the system for work

The system is prepared for work by connecting the power lead and accessories.

As the only one, the power lead can be connected and disconnected only when the system is switched off. The system should be supplied from a socket equipped with an earth bolt. The supply socket is located in the back wall of the encasing (Fig. 4, item 5).
The system does not require connecting the additional grounding pin. It is used for grounding if a non-grounded socket is used or in sites where the system of protection against electric shock requires such connection.
The pedal is connected to socket 7 in the back wall of the encasing (Fig. 4).

The connection mode of the accessories is explained in Fig. 5.
The neutral electrode is not required for bipolar operations.
More information about the neutral electrode can be found in Section "6.2. Neutral electrode control".



Power settings
Prior to an operation the correct power should be set. It is set independently for the operations of cutting, coagulation and bicoagulation. The maximum wattage is indicated on displays assigned to each type of operation. The settings are changed by arrow-marked keys.

Before the first use of the system it is well-advised to become familiar with the effects of different settings by performing tests on fresh beef.

6. System operation and the performance of electrosurgical operations

6.1. Switching on

The system is switched on using a mains switch 1 (Fig. 3). The accessories can also be connected to the system when it is on, obviously while keeping appropriate safety conditions. At this point, care should be taken to prevent a possible switch-on of the generator by accidental pressing of the push button or pedal.

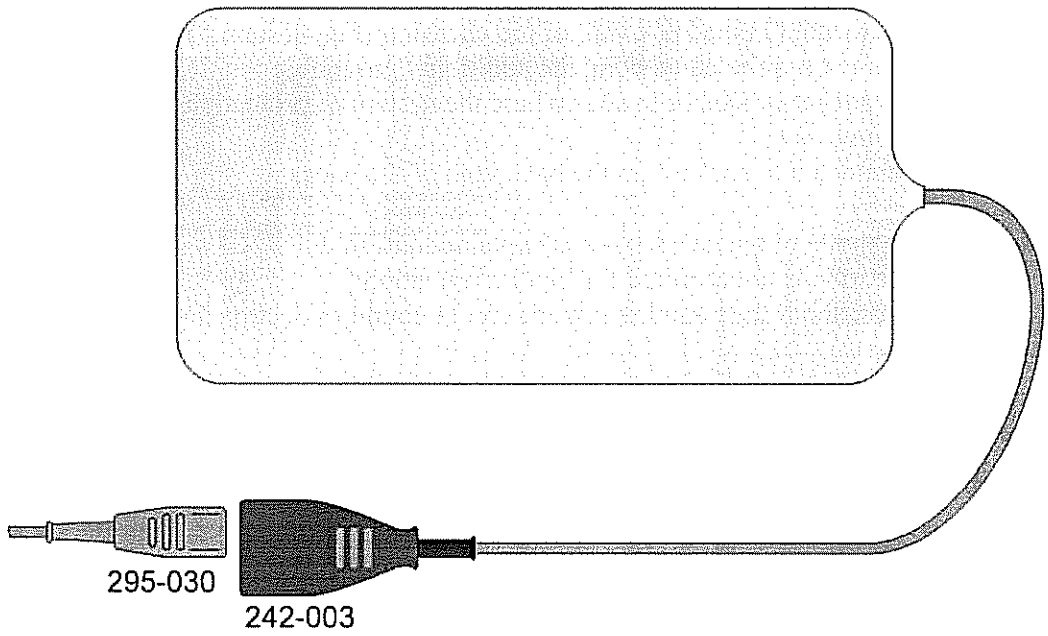


Fig. 6. Connection of a reusable neutral electrode

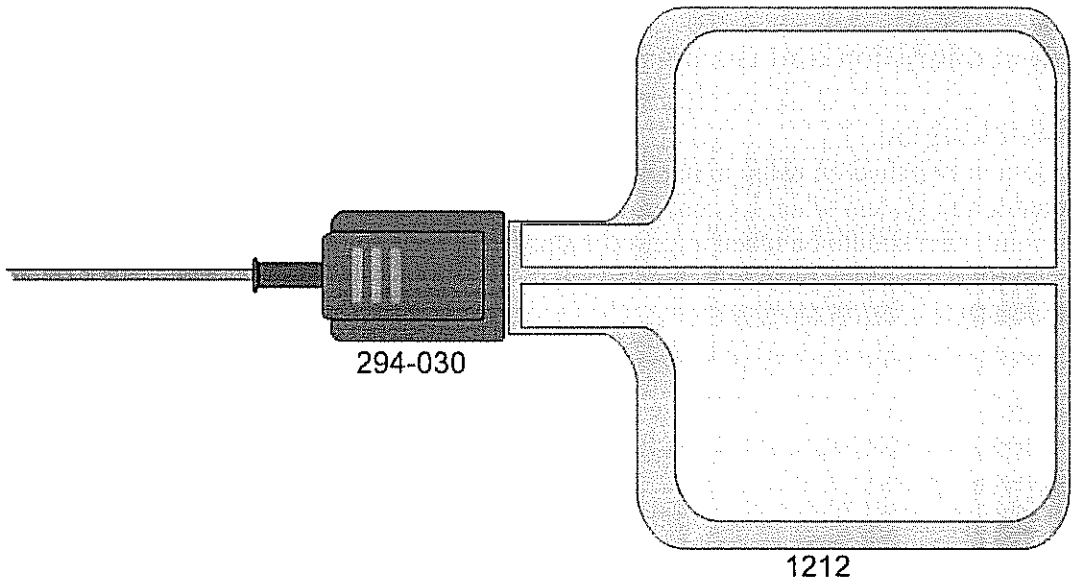


Fig. 7. Connection of a disposable neutral electrode

6.2. Neutral electrode control

In the monopolar operation mode, the system controls correct connection of the neutral electrode cables. The electrode application quality is shown on 8 LED linear indicator **D4 (Fig. 3)**.

A significant advantage of the neutral electrode control system is the fact that the control is performed continuously, also during generator operation. The neutral electrode control system has no effect on bipolar mode operation.

- One-piece, reusable neutral (rubber) electrode

has no feature of controlling the application, i.e. adhesion to the patient's body. Only correct connection of the electrode to the system is controlled. With correct connection, all LEDs on linear indicator **D4 (Fig. 3)** should be on.

Therefore, when using one-piece rubber electrodes, special attention should be paid to correct placement of the neutral electrode, to prevent burns in its application site during the procedures.

- The electrode should adhere to the body with the entire surface and be fixed to prevent accidental movement.
- The electrode may not be positioned with a corner towards the operating field.
- The electrode may not be wet or wrapped with anything.
- No fluids may enter between the body and the electrode.
- It should be remembered that rubber electrode looses its conductive properties over the time due to washing out of active substances from the rubber. Such electrode increases the risk of patient burn. Therefore, reusable electrodes should be sent to periodic inspections along with the systems.

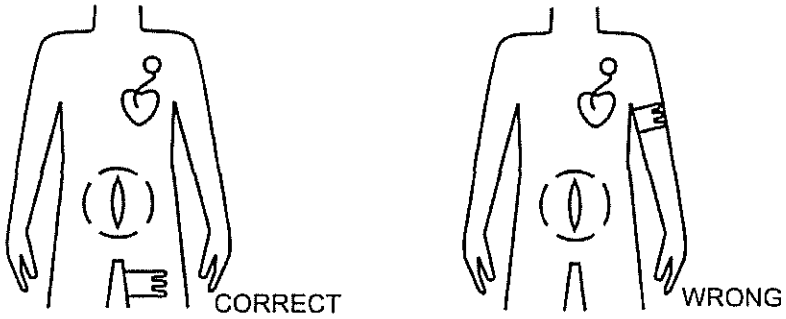
Neutral reusable electrodes should be disinfected before use (see Section 9 "System maintenance").

The medical practice shows that the patient is best protected against burns by the use of splitted single-use electrodes.

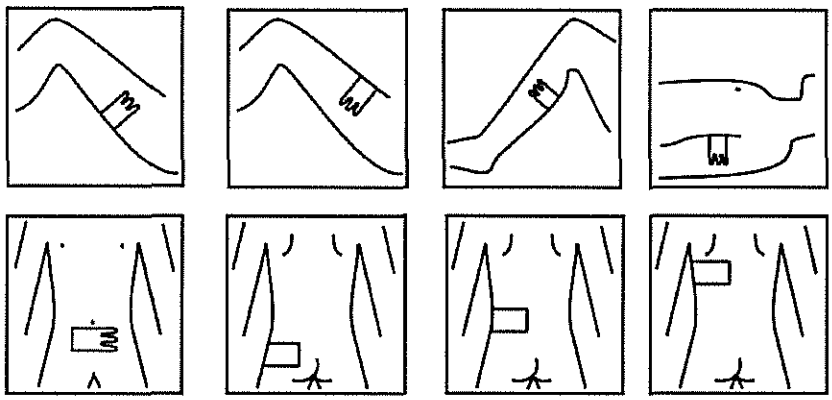
- Splitted, single-use neutral electrode

enables to control neutral electrode application. The risk of burns from this electrode is therefore significantly limited. Maximum resistance at which the system will operate is 240 Ohm. In practice, it means that at least one green LED must be on in the linear indicator. If an attempt to use the generator is made when the electrode application is not adequate, the device signals the fact with modulated sound.

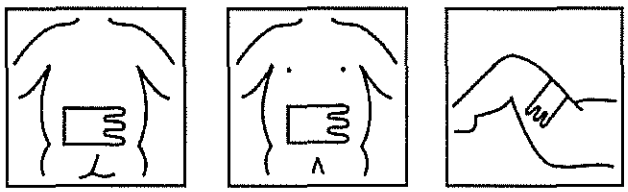
Consult instructions for use provided on the single-use electrode packaging.



Mode of neutral electrode's application at the patient with a pacemaker.



Correct neutral electrode's application areas at the adult patient.

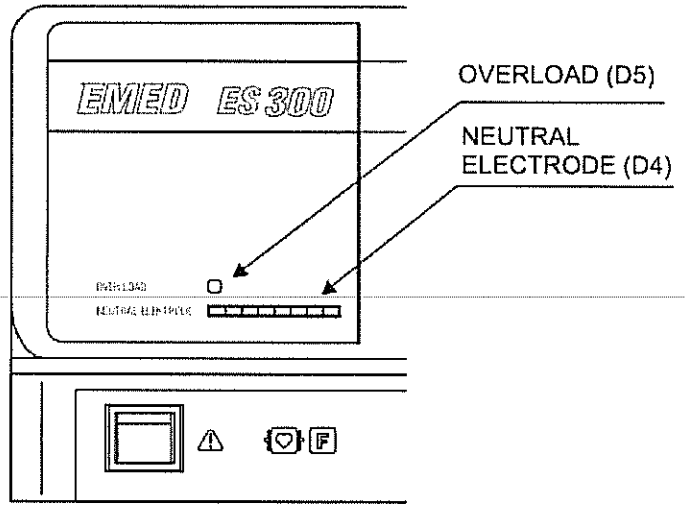


Correct neutral electrode's application areas at the child.

6.3. System overload control

The system has a working time limit, protecting it from overload (OVERLOAD). The limit depends on the set power and the type of operation. In practice, for a pure cut the overload control allows for operation with a rate of 33%, i.e., for 1 minute of work and 2 minutes of break for the full power of 250 W.

- System overload
is signalled by the lighting of the red-coloured overload controller. The system then forces an end to the operation until the controller goes out (about 30 seconds). With attempts to continue cutting or coagulation, a pulsed, unmodulated sound will be heard, indicating overload.



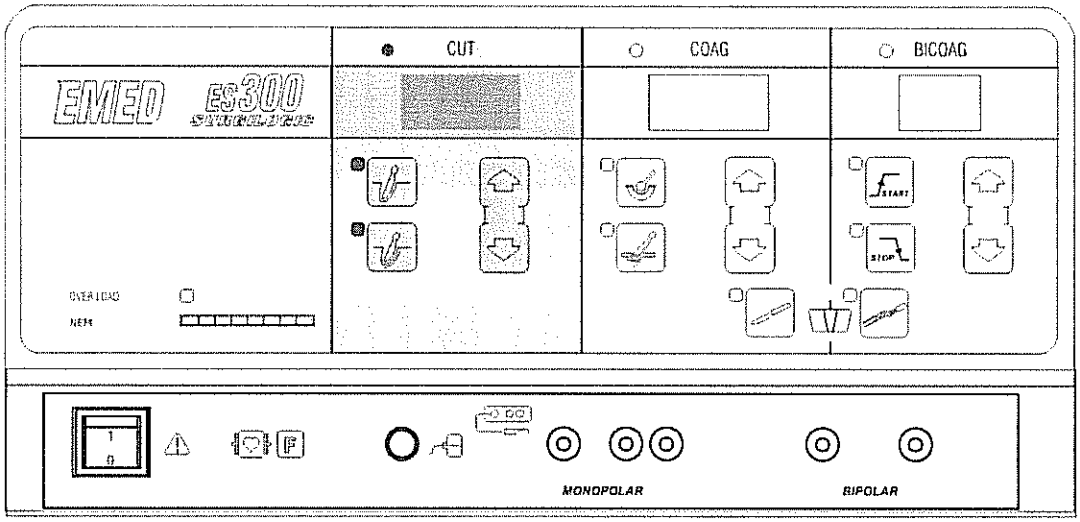


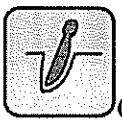
Fig. 8. Cutting power display and push-buttons for cutting types and power regulation

6.4. Monopolar cutting

As a rule, cutting is performed by a knife or loop electrode.
The manner of connecting electrodes is explained in Fig. 5.

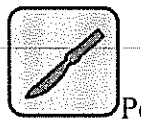
Prior to cutting the kind of expected effect should be selected: pure cut or one with hemostasis. The selection is made with push-buttons K1 and K2.

Pure cut (**K1**)


Cutting with hemostasis (**K2**)

Cutting with hemostasis (blend) intensifies the coagulation of the edges of the tissue being cut.

In the cutting mode the system is switched on by the yellow-coloured push-button in the electrode handle or the yellow-coloured push-button of the pedal. In order to cut using the pedal, it should be set for the monopolar work mode (with push-button **K13**).


Pedal for monopolar operations (**K13**)

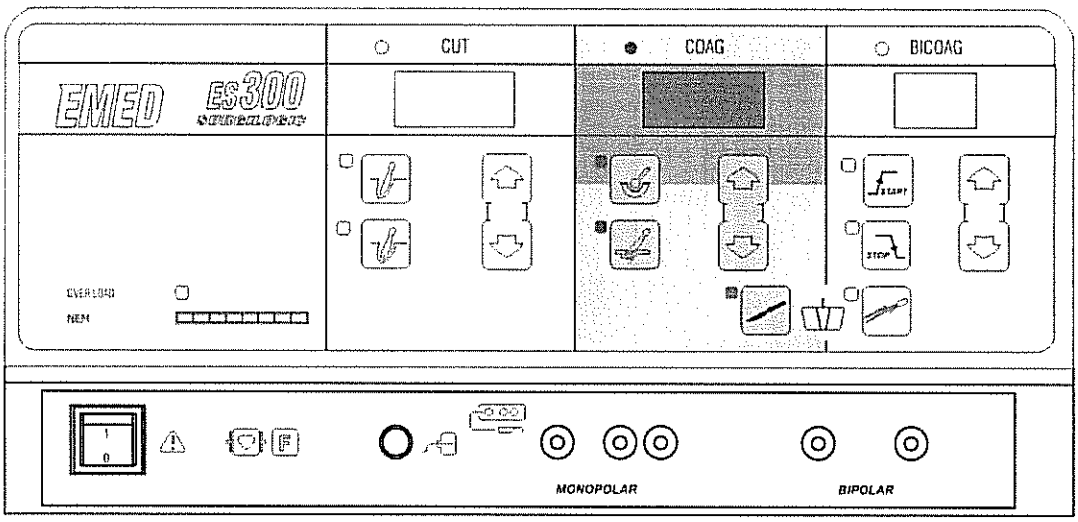


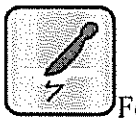
Fig. 9. Coagulation power display and push-buttons for coagulation types and power regulation

6.5. Monopolar coagulation

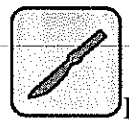
As a rule, coagulation is performed with a ball or plate electrode.
The manner of connecting electrodes is explained in Fig. 5.

Prior to the operation the type of coagulation should be selected: soft coagulation or forced coagulation. The selection is made with push-buttons K5 and K6.

Soft coagulation (**K5**)


Forced coagulation (**K6**)

In the monopolar mode the system is switched on by the blue-coloured push-button in the electrode handle or the blue-coloured push-button of the pedal. In order to use the pedal, it should be set for the monopolar work mode (with push-button **K13**).


Pedal for monopolar operations (**K13**)

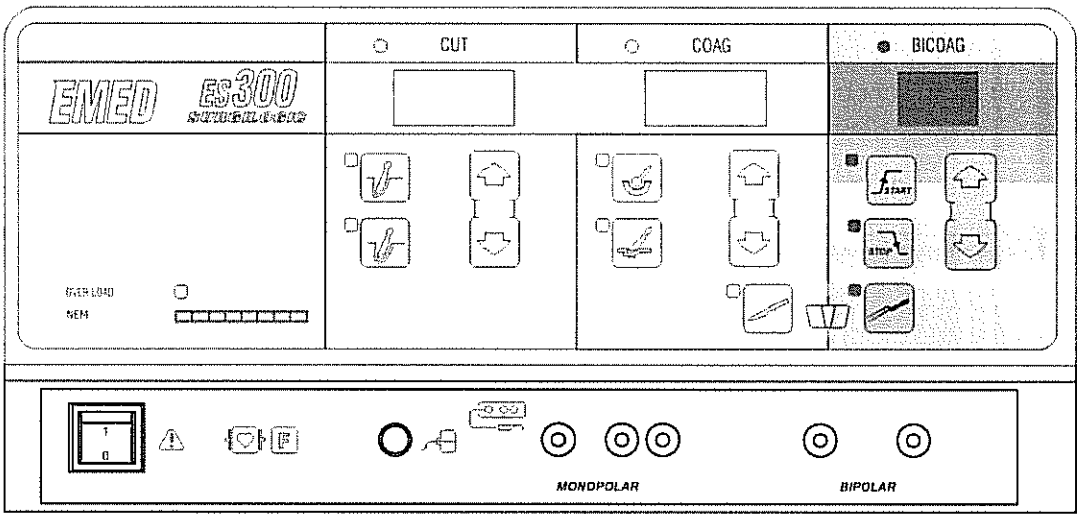


Fig. 10. Bipolar coagulation power display and push-buttons for time limit and power regulation

6.6. Bipolar coagulation

The manner of connecting electrodes is explained in Fig. 5.

In the bicoagulation mode the system can be switched on in two ways - automatically after tissue has been grasped and using the pedal.
Automatic work occurs when the push-button K10 is switched on.

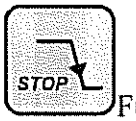
Bipolar automatic start (**K10**)

When tissue has been grasped and 1 second has elapsed, the generator switches on. It switches off when pliers come apart or tissue has coagulated.

Pedal-controlled work is possible after the pedal has been set for bipolar operation with push-button K14.

Pedal for bipolar operations (**K14**)
In this mode the surgeon controls the beginning and end of coagulation.

In addition, it is possible to use a function, which limits the coagulation time to 1 second. This function is switched on and off with key K9 (Fig. 3).



Function limiting the operation time in the bipolar coagulation mode (**K9**)

6.7. Switching off the system

After finishing the operation the system should be switched off with the mains switch 1 (Fig. 3) and the plug should be removed from the mains socket. After the system has been switched off the electrodes and pliers should be disconnected from cables, and then the electrode cables should disconnected from the system.

7. Means of protection and warning

7.1. During electrosurgical procedures, the **risk of burns** should be minimised by:

a) using only compatible accessories according to the description (see Section **1.1.**),

b) checking the connecting cables of application electrodes each time, and especially their insulation,

c) careful application of the neutral electrode (see Section "Neutral electrode control"),

d) preventing any fluids from entering between the neutral rubber electrode and the patient's body,

e) protecting the patient against contact with metal and grounding elements,

f) avoiding touching the patient's skin – e.g. dry gauze should be used as an insulator, if necessary,

g) the patient's individual body parts may not be in contact (e.g. hand to thigh),

h) the neutral electrode should be applied as close to the procedure site as possible,

i) bipolar technique should be used during procedures performed on body parts (organs) which have narrow connections with the rest of the body.

7.2. During procedures performed in **patients connected to monitoring devices (ECG)**, the monitoring electrodes should be placed as far as possible from the electrosurgery electrode application sites. Moreover, it is recommended to use monitoring devices equipped with protection systems against high-frequency currents.

7.3. The application electrode cables should be connected in a way not to:
- touch the patient,
- be intertwined with other cables.

7.4. During procedures in which high-frequency current could flow through **low cross-section** body parts, bipolar technique should be used to minimise the risk of accidental coagulation.

7.5. The output power setting should not exceed the power necessary for a given procedure.

7.6. Evident **output power drop** with normal settings may indicate incorrect application of the neutral (rubber) electrode.

7.7. Soiled active electrodes may impair the operating quality of diathermy.
It applies in particular to soft and bipolar coagulation.

7.8. Flammable anaesthesiological agents and oxidative gases (such as N_2O or O_2) should be avoided. If they must be used, particular caution should be exercised.

7.9. Non-flammable disinfectants should be used. Otherwise, they should be left to evaporate before the procedure. There is also a risk of spilling these agents under the patient's body or into the body cavities. In this case, the affected places should be carefully dried. A flammable agent may ignite from a sparkle occurring during normal operation of the system.

7.10. Sparkles at the active electrode pose a risk of ignition for dressings and metabolic gases.

7.11. During the procedures, there is a risk of malfunction or **damage of a heart pacer.** In these patients, bipolar technique is recommended. Prior to electrosurgery, seek an advice of an authorised representative of the pacer manufacturer. The use of electrosurgery systems is not allowed in patients with heart pacers in outpatient settings.

7.12. It should be remembered that reusable accessories enclosed to the system **are not sterile.**

7.13. High-frequency leakage currents may cause burns in locations distant from electrode application sites, if the places are in contact with conductive elements.

7.14. The frequently used technique of coagulation "through the instruments" should only be performed using appropriate insulated pliers. There are special pliers with insulated handle (contact EMED representatives for additional information). Surgical gloves do not protect the operator from burns adequately. Spray coagulation should not be used in this technique.

7.15. When using spray coagulation, a safe distance from the fingers and metal parts of endoscope/fiberscope optical parts should be maintained.

7.16. During the construction of electrosurgery systems, EMED paid special attention to EMC requirements which are becoming more restrictive. As a result, solutions ensuring minimum emission levels to meet current and future requirements have been selected. Laboratory measurements have confirmed high electromagnetic safety level of the EMED diathermy.
In typical operating conditions, a field corresponding to 8-hour daily exposure occurs at a distance of 5 to 15 cm from working cables. Above 20–40 cm, the field decreases to an admissible value without time limit. The electromagnetic fields occur mainly around the cables, the diathermy itself is practically not an emitting component.
During breaks in operation, diathermies do not emit any high-frequency power. As the field distribution depends on a specific stand, equipment and cable arrangement, you may ask a local unit for diseases control and prevention to determine a detailed distribution of the emission zones.

8. Checking the technical condition

After each operation the condition of power leads, electrodes and the pedal switch should be checked.
A more accurate inspection of the technical condition should be performed by an authorised producer's service.

After switching on of the unit the Power On Self Test is performed:
If any error occurs it is displayed in a form below

Err XXX 00

where XXX means malfunction of
01 – Handle switch CUT,
02 – Handle switch COAG,
04 – Foot switch CUT,
08 – Foot switch COAG,
16 – Bipolar circuit shorted.
If any other code is given an authorised service should be contacted.

9. System maintenance

CLEANING

The system should be cleaned in a way to prevent any liquid from entering inside.

ACCESSORIES STERILISATION

Sterilisation should be performed according to the recommendations of a specific accessory supplier.
The accessories supplied by the manufacturer, unless specified otherwise, are non-sterile and require sterilisation before use.

The offered electrosurgery accessories, unless specified otherwise, may be steam sterilised at up to 134°C at 2.3 Bar. If other accessories are used, the manufacturer's instructions should be observed.

FUSE REPLACEMENT

The fuse sockets are located in the back panel (Fig. 4). WTA-T 4A, 250V fuses (20 mm size, F type) should be used. To replace the fuses:
- disconnect the system from the mains,
- unscrew the fuse sockets using flat screwdriver,
- replace the fuses.

9.1. Recommended agents for cleaning and sterilisation of multiple-use electrosurgical accessories

1. MANUAL CLEANING

The components strongly soiled with the remaining tissues should be pre-cleaned using a plastic cleaning plate or plastic brush. Then one of the following recommended agents should be used:

Manufacturer	Product
Braun Melsungen	Stabimed Helipur H plus N Prontocid N
Henkel Hygiene	Sekucid konz. Sekusept forte Sekusept forte S
Johnson & Johnson	CIDEX
Schuelke & Mayr	Gigasept FF Lysetol FF
Anios	Aniosyme PLA Salvanios PH10

For disinfection of neutral (rubber) electrodes, we recommend:

Manufacturer	Product
Henkel Hygiene	Incidin perfekt Minutil Incidur F

2. MECHANICAL CLEANING

Manufacturer	Product
Henkel Hygiene	Sekumatic FR / Mycie Sekumatic FRE / Mycie Sekumatic FD /Dezynfekcja
Schuelke & Mayr	Thermosept RKF / Mycie Thermosept DK / Dezynfekcja
Dr Weigert	Neodisher FE / Mycie Neodisher Septo DN / Dezynfekcja

CAUTION!

To avoid mechanical damage, electrode handles should not be dried in compressed air under pressure exceeding 3 bar.

3. AUTOCLAVE STERILISATION

Multiple-use products are designed for autoclave sterilisation (according to DIN 58946):

- **temperature: 134°C,**
- **time: 20 minutes,**
- **pressure: 2 bar.**

4. DO NOT USE FORMALDEHYDE STERILISATION.